

VMBIP, VIM, COD IAP Meeting April 17, 2008

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State Roll-Out Plan

- Meeting with CDC for Pre-Go-Live prep
- Present information at IAP Meetings
- Reports & Handouts Review
- Conference Calls with LHDs
- MCIR Meetings
- Complete Check-list
- Go Live...May 12th, 2008!

CDC & McKesson Meeting

- Pre-go-live meeting was yesterday
- State reviewed process with MCIR
- CDC reviewed steps to complete
- MCIR development continues

Reports and Handouts

- Review guidelines for Providers and LHDs
- Review new MCIR report functions
- Discuss the plan for a paper back-up system

Principles of Provider Participation

- LHDs are the point of contact for provider enrollment and participation
- Providers must have a current, physician signed VFC Enrollment form, Profile and MMRV/Varicella agreement, and Storage Capacity Survey
- LHDs must complete VFC Enrollment Site Visit and Review Emergency Response Plan
- LHDs are the point of contact for all provider quality assurance and accountability activities

Principles of Provider Participation continued...

- By signing the VFC Provider Agreement, the provider agrees to adhere to the vaccine accountability and quality assurance requirements of the agreement
- Providers must ensure accurate shipping information is updated to the LHD anytime a change occurs (e.g., correct current ship to address, any special shipping instructions, receiving hours and contact information)

Principles of Provider Participation continued...

- Availability of vaccine brand(s) will be determined by MDCH and identified on the standardized order form
- In the event of a shortage of a specific brand of vaccine; under the guidance of the CDC and/or MDCH, McKesson may distribute any available product
- All VFC providers must participate in MCIR
- All providers must submit supporting documentation when ordering vaccines

Provider Ordering Frequency and Forms

- All orders shall be submitted in MCIR or on the standardized paper vaccine order form provided by MDCH VFC program. The order forms can be customized by LHDs to include LHD logos and contact information.
- Providers should order according to the LHD designated interval and include all needed antigens at that time, using MCIR or the MDCH approved order form

Provider Ordering Frequency and Forms continued...

- Providers will order on a regularly scheduled basis determined by their local health jurisdiction
 - Most all VFC providers have been assigned, now CDC is having Michigan determine order frequency for new providers
- Primary ordering schedules are:
 - Monthly
 - Bi-Monthly
 - Quarterly

Establishing Provider Ordering Frequency: LHD Role

- LHDs to evaluate provider storage capacity and usage patterns in determining provider ordering frequency and pattern. New providers should be placed on quarterly ordering schedule, if storage allows, until needed amounts are established
- LHDs approve provider ordering frequency, pattern and inventory standards and monitor provider adherence to them
- LHDs with an established pattern for submitting orders (by the 5th of the month, or second week of the month) can continue

Establishing Provider Order: Provider Role

- Review pt. records from the same months in prior years to determine the amount of vaccine they will administer during an interval
- Monthly Doses Admin. Reports can help determine monthly need for each antigen
- Providers orders should include only enough vaccine to maintain the correct level of stock based on their ordering frequency and storage capacity plus a 15-30 day reserve stock (e.g., If a provider orders monthly, they determine what they need for the month, and what is needed to maintain a 15-30 day reserve stock)

Establishing Provider Order: Provider Role continued...

- Inventory on hand must be calculated to determine the overall vaccine need and must be submitted at the time an order is placed
- A simple description of the order determination process is:
 - Reserve stock + (plus) doses expected to be administered during the interval – (minus) doses in inventory = (equals) approximate order size

Calculation	Data Needed to Calculate Order	Example (monthly order + 30 day reserve)
	# of doses needed to maintain reserve stock (by antigen)	100 doses
Add	# of doses expected to admin during interval	100
Equal	Total Vaccine Need for Interval	200 doses
Subtract	Inventory on Hand	120 doses
Equal	Vaccine to Order	80 doses

Calculating Provider Order

- Apply the calculation to each antigen to determine the order for each antigen
- Providers should note any special circumstances (kindergarten round-up, special clinics, etc.,) resulting in an increased need for vaccine

Calculating Order Frequency

Provider Size Based on Annual Usage (all antigens)	Order Frequency Category	Number of Doses Per Month
High Volume 2000 doses per yr	Monthly (12 times per yr)	170 - 417 Storage Need 170 - 417 doses
Medium Volume 500 – 2000 doses per yr	Every other month (6 times per yr)	42 - 170 Storage Need 42 - 170 doses
Small Volume Less than 500 doses per yr	Every third month (4 times per yr)	3 – 42 Storage Need 9 – 126 doses

Ordering Frequency

- LHDs can recommend adjusting provider order frequency and size based on special circumstances:
 - Providers with low monthly usage needs and insufficient storage space to maintain a 3 month inventory may order more frequently than 3 months
 - Monthly is the most frequent a provider can order
 - Boxes can be broken down to quantity of 5
 - DT can be ordered in a quantity of 1

Exceptions to Ordering Frequency

- LHDs can allow exceptions to the established schedule and pattern under special circumstances when necessary to prevent the disruption of immunization services
- Exceptions resulting in more vaccine orders than the established provider ordering schedule will be considered priority orders
- LHDs will communicate with MDCH on all priority orders to facilitate request
- MDCH will place the priority order

Priority Orders

- Priority Ordering should be the exception:
 - provider has a vaccine loss
 - emergency outbreak
 - vaccine shortage
- Priority orders can be processed and shipped within 24 hours of placement with McKesson
- To expedite the order and to assure prompt processing and delivery, providers must contact their LHD immediately about the priority order

Priority Orders continued...

- LHDs will follow-up with the provider on all priority order requests as a quality assurance consultation to remediate the conditions leading to the priority order
- Repeated priority orders due to inadequate order planning, storage and handling issues, or other vaccine quality assurance problems may result in an LHD site visit for possible corrective action
- MDCH VFC is available upon request to support LHDs regarding priority orders and follow-up

Assessing the Appropriateness of an Order

To determine whether or not a provider order is within reasonable parameters, LHD staff are to:

- Review provider historical ordering/usage data
- Review provider inventory reports when orders are submitted
- Compare existing inventory with doses administered data or typical usage data for the order period (e.g., 1 months for providers ordering monthly, 3 months for providers ordering quarterly etc.)

Assessing the Appropriateness of an Order continued...

- Know the number of doses of reserve stock each provider should maintain to have 30-45 day supply on hand
- Identify any unusual circumstances warranting an increased order
- Review provider success with vaccine storage and handling quality by assessing submitted temperature logs
- MDCH is available for consultation regarding the appropriateness of provider orders

Order Approval: Authority, Process, and Appropriateness

- LHDS have the authority for approving provider orders within their counties
- When LHDs receive provider orders, the shipping address and instructions should be verified to ensure accurate delivery
- LHDs will review provider orders for appropriateness (timing of order, size of order, antigens ordered, etc.)

MDCH Order Processing

- MDCH will receive orders by:
 - MCIR VIM/COD
 - Fax (if using back-up system)
- MDCH to approve LHD orders
- MDCH to enter back-up orders for all VFC providers if e-ordering is delayed
- Once an order arrives at MDCH, it is assumed LHDs verified and approved the order

Order Approval: Authority, Process, and Appropriateness continued...

- LHDs to review provider compliance with submission of supporting documents when determining how to process the order
- LHDs may approve orders as submitted by providers or hold the order for review. If the LHD determines that the order is incorrect, or not appropriate, the LHD will hold for review, discuss the order with the provider, and adjust if necessary. Orders must be processed in a timely manner.

Order Approval: Authority, Process, and Appropriateness continued...

- Once the LHD approves the order, the LHD will submit the order to MDCH for processing. LHD approval of the order is assumed when the order is submitted to MDCH for processing.
- Frozen vaccines will be ordered on the same order form, using the same ordering pattern and frequency of all other vaccines
- Frozen vaccines will be shipped via Merck
- Providers to verify shipment by adding Merck frozen vaccine into inventory at arrival

Order Processing

- Provider orders will be placed with LHDs for approval and processing
- LHDs may receive orders by:
 - MCIR VIM/COD (if not available)
 - Fax
 - Phone
- LHDs will monitor and approve orders based on supporting documents:
 - Temperature Logs
 - Inventory Forms
 - Doses Administered Reports

Order Processing continued...

- LHDs to check MCIR for orders at least twice a day
 - Once in the AM
 - Once in the PM
- MDCH will receive orders by:
 - MCIR VIM/COD
 - Fax of approved individual orders from LHDs
 - MDCH will process orders daily

Order Processing continued...

- LHDs to determine who will assess and approve orders, will have MCIR Administrative Level Access:
 - Many use experienced clerks
 - Some require Imms Nurses or experienced staff
 - All should understand review process, verification of supporting documents
 - Suggest several people trained in processing orders to cover for vacations and illnesses
 - MCIR ID will be used for LHD locations to approve provider orders

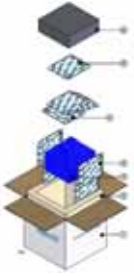
Receiving Guidelines

- LHDs will monitor shipments to private providers
- All vaccines ordered via McKesson will be delivered either to LHDs (if still placing LHD depot orders), individual providers or both based on LHDs roll out plan
- Each provider office should have at least 2 people trained for vaccine ordering and receiving
- LHD contact information should be posted with VFC providers receptionists who typically receive UPS and FedEx shipments

Receiving Guidelines continued...

- Provider offices should post signage directing UPS and FedEx delivery personnel to not leave vaccine deliveries unattended
- All provider staff must be trained to ensure vaccine deliveries are received by the appropriate person, and stored immediately
- Failure to appropriately store vaccine upon delivery will result in a possible vaccine loss for the provider and corrective action plan
- PPOC (Primary Point of Contact): translates to Local Health Department
 - PPOC is McKesson term-need to educate providers

Box Pack Out Example



- Recyclable, insulated container
- Validated to maintain 2-8 degrees Celsius for up to 72 hours
- Boxes clearly marked to refrigerate upon arrival
- Postage paid labeling included to facilitate container pick up
- Vaccine in Zip-Loc bag

Box Example



Carrier Delivery Instructions



Receiving Guidelines continued...

- When vaccine arrives, shipping invoice should be reviewed and vaccines compared:
 - Lot numbers should match
 - Number of doses and antigen types should match
 - Expiration dates should match, and should be at least 6 months from date of receipt
 - Package should be without damage
 - Temperature monitors must be within acceptable limits
 - Refrigerator temperature monitor
 - Frozen temperature monitor

Provider Information		Shipping Information	
Provider ID #	SHIP TO	SHIP TO	SHIP TO
Number of Containers	SHIP TO	SHIP TO	SHIP TO
Presentation	SHIP TO	SHIP TO	SHIP TO
Container Number	SHIP TO	SHIP TO	SHIP TO
Manufacturer	SHIP TO	SHIP TO	SHIP TO
Ship Date	SHIP TO	SHIP TO	SHIP TO
Lot #	SHIP TO	SHIP TO	SHIP TO
Doses by Presentation	SHIP TO	SHIP TO	SHIP TO
Vaccine Price	SHIP TO	SHIP TO	SHIP TO

In-Package Flier Supports Contractual Communication Requirements

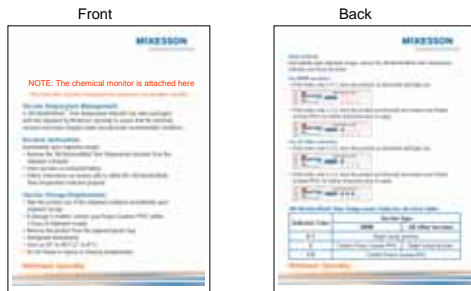


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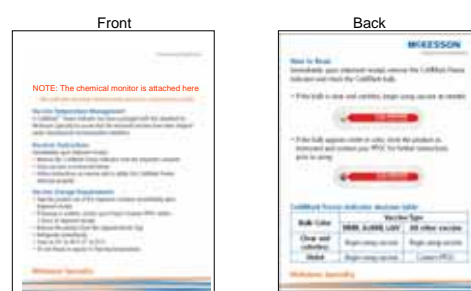


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In-Package Instructions: 3M™ MonitorMark Time Temperature Indicator



In-Package Instructions: ColdMark™ Freeze Indicator



Receiving Guidelines continued...

- Contact the LHD immediately if:
 - Any of the previous mentioned criteria is not met
 - Any concerns that the cold chain was not maintained
- LHDs to contact MDCH to follow-up with McKesson regarding problems with vaccine orders
- "Signature on file" arrangement issue
- McKesson will include flyer about packing list and how to return boxes...



Delivery Timelines

- Vaccine delivery will typically occur within 10-14 days of the time the providers order is placed with McKesson
- Vaccine delivery could occur as soon as 5 days and as long as 3 weeks from time of order placement with McKesson
- Information on vaccine shipments will be in MCIR via electronic transmission
- Providers will verify shipment delivery
- LHDs will contact MDCH for follow-up with McKesson regarding vaccine delivery issues

48 Hour Rescue Process

- The objective of this process is to save as much vaccine for the program as possible
- McKesson will proactively track delivery status of every order
- At the 48 hour mark, McKesson will intercept product and bring it back due to lack of delivery
- A call to MDCH will occur to communicate events
- MDCH to confirm shipping info and ask for reshipment of order

How to Return Empty Boxes

- Take the ice bricks out of the box and throw away
- Replace the foam / Styrofoam lid on the cooler
- Reverse the flaps so the UPS A.R.S. label is visible on the outside of the box
- Seal the box with packing tape
- Give the box to UPS driver that is picking up or dropping off deliveries
- Never call UPS for pick up

Vaccine Transfers

- LHDs may coordinate vaccine transfers from providers to LHD, or provider to another provider
- LHDs can **only** coordinate transfers within their counties due to VIM (must choose PIN # that it will be transferred to)
- MDCH Field Rep of the county that needs to transfer out to another county will complete transfers from county to county
- Transfers should only occur with shortages, and/or redistribution of flu or soon to expire vaccines

Vaccine Inventory

- LHDs will have 3 inventories
 - LHD clinic inventory
 - LHD private stock inventory
 - LHD Depot inventory for providers until all are ordering via McKesson
- LHDs will be assigned 2 MCIR sites
 - One for LHD clinic
 - One for LHD depot
 - This will be maintained, after depot closes, just for All Hazard purposes

Vaccine Inventory continued...

- LHDs will be assigned a depot PIN #
- LHD Depot PIN #'s will be easy to identify and can be inactivated as the depot is no longer in operation
- The LHD Depot MCIR ID will remain, and only used again in the case of an All Hazard event

Vaccine Inventory Reconciliation

- Process still in production and final design
- Transactions will create loss or wastage report if indicated
- If wastage report is present, LHD must view provider inventory to determine if vaccine loss report is indicated, education is needed, etc.
- MDCH to have view option and final say on wastage reports
- More to come on this as it is ready...

VFC Reports in MCIR

- Currently New VIM can provide:
 - VFC Profile
 - VFC Doses Administered Reports
 - Ending Inventory
 - Physical Inventory Report
 - Refrigerator Count Report
 - Additional reports to follow in later roll-outs including:
 - Health Care Management Report (Super-User)
 - More options for reports

Universal Birth Dose Hep B Plans

- Plans are to keep process simple for Birthing Hospitals to continue with program, no MCIR VIM
- Continue to have them place orders through LHDs until birthing facility ordering features are in place
- LHDs encouraged to keep birthing hospitals on same ordering frequency as now
- Assure you have depot supply for hospital orders, until they are transitioned to McKesson ordering
- LHDs to receive temp logs from hospitals
 - Work with hospitals on accepting their logs if all information is correct for VFC
- Future instructions and protocols to come

Paper Back-Up System

- In the event we do not have e-ordering up and functional at our "go live" date:
 - VFC will have an updated order form to include new presentations
 - Providers will use the form to order on their assigned ordering schedule
 - Supporting documents will be sent to LHDs for review

Paper Back-Up System continued...

- LHDs will approve orders and use MDCHVariorder@michigan.gov e-mail address to submit orders to MDCH
- MDCH will receive orders via e-mail
- MDCH VFC will fill orders with MDCH Depot and possible McKesson
- MDCH will submit orders to McKesson
- MDCH respond with e-mail to LHD to indicate order was received and indicate if order will come from MDCH Depot, McKesson or both

MDCH Depot

- All orders beginning May 1, 2008 will be sent to MDCH VFC, not Depot
- Inventory will spend down via the previously stated system
- MDCH Depot expected to close June 30, 2008
- State purchased vaccines will be placed at McKesson, or be on a replacement schedule

LHD Depots

- LHDs can continue to place orders for their depots until providers have transitioned to McKesson, using VFC Depot PIN #
- LHDs will see a decrease in their storage of vaccines in their depots as providers transition to McKesson
- LHDs to review orders and see what they want to fill from their depot first and then use McKesson to provide the rest of the order, to help deplete LHD depots inventory
- If we are using paper system, only orders that need to go to McKesson should be sent to MDCH for processing
- LHDs may need assistance from Field Reps to completely use up depot stock
- LHDs will need to place orders with MDCH for their own clinic inventories, using their VFC PIN #

Key Messages to Communicate to Providers:

- Translate Acronym on McKesson written materials: PPOC is LHD
- McKesson does not ship direct-ship vaccines
- Vaccine boxes used by McKesson are stable for 72 hours
- McKesson has 8 different size boxes
- Shipments can arrive in more than one box
- Boxes should arrive at the same time
- Have providers call PPOC (LHD) on Day 1 of partial or split shipment
- FedEx and UPS will ship boxes

Key Messages to Communicate to Providers: cont...

- Allow for lead time of up to 3 weeks
- Expect vaccine deliveries on Monday and Friday, if provider is open on those days
- Review Chemical Temp Monitors
- Call LHD within 1 hours of receipt for any order exception or temperature monitor issue
- MDCH needs to call McKesson within 2 hours of delivery to provider if possible

Key Messages to Communicate to Providers: cont...

- Flu will be shipped separately from other vaccines
- Due to Hib shortage, Hib vaccine will be shipped incrementally throughout the month
- Expired vaccines should be returned to MDCH Depot by May 12th for excise refund
- After May 12th Expired vaccine will be sent to McKesson
- Can return expired vaccine in box that is to be returned to McKesson, must include return form and LHD must know about vaccine expiration

Key Messages to Communicate to Providers: cont...

- Only UPS will pick up boxes to be returned to McKesson
- NEVER CALL UPS DIRECTLY, it will result in charge to the provider from UPS
- Contract with UPS is with McKesson for box returns
- McKesson customer service can be contacted for Empty Box Return Coordination if necessary

More to come...

- More information will be coming to you as we get closer to going live
- Please remain up to date on e-mails as this is our main form of communication
- Changes will occur
- MCIR is still designing our final product and it will come in phases
- Remember you don't have to distribute flu vaccine this year!!!